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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/713,183	11/14/2003	Dean L. Engelhardt	Enz-52(D2)(C)(D1)	5179

28171 7590 04/01/2009

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EXAMINER	
SALMON, KATHERINE D	
ART UNIT	PAPER NUMBER
1634	

MAIL DATE	DELIVERY MODE
04/01/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/713,183	ENGELHARDT ET AL.	
	Examiner	Art Unit	
	KATHERINE SALMON	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 January 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *112-120,123-130 and 133-148* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *112-120,123-130 and 133-148* is/are rejected.

7)☒ Claim(s) *141 and 142* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *1/27/2009, 1/21/2009*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. This action is in response to papers filed 1/21/2009.

2. Currently Claims 112-120, 123-130, 133-148 are pending. Claims 1-111, 121-122, 131-132 are cancelled.

3. The following rejections for Claims 112-120, 123-130, 133-148 are newly applied.

4. This action is non-final

Withdrawn Rejections

5. The rejections to the claims under 35 USC 103(a) made in sections 10-11 are withdrawn.

6. The terminal disclaimer filed on 1/21/2009 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of 10/718391 has been reviewed and is accepted. The terminal disclaimer has been recorded.

Claim Objections

5. Claims 141-142 are objected to because they depend from cancelled claims. The claims should be amended to depend from an amended claim or the claims should be amended to incorporate the cancelled subject matter. As such the claims have not been further treated on the record.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claim 112-120 and 141-142 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 112-120 are indefinite. Claim 112 recites the limitation "said nucleic acid of interest" in line 3 of step d. There is insufficient antecedent basis for this limitation in the claim. It is suggested that the claim be amended to e.g. said DNA molecule of interest.

Claims 141-142 are indefinite. MPEP 608.01(n)[R-3](V) states that “If the base claim has been cancelled, a claim which is directly or indirectly dependent thereon should be rejected as incomplete”. Herein the instant case Claims 141-142 are dependent upon Claim 91 which has been cancelled.

Claim Rejections - 35 USC § 112/New Matter

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8. Claims 146-148 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 146-148 are rejected as failing to comply with the written description requirement. Upon review of the specification, the specification does not appear to provide support for the recitation of “a reverse transcriptase having RNase H activity" in Claim 146. In response to the amendments, applicants have not pointed to any particular teaching in the specification.

The instant specification provides support for an effective amount of a reverse transcriptase, but does not limit the reverse transcriptase to having RNase H activity. Schuster et al. (US Patent 5169766 December 8, 1992) teaches that reverse transcriptase can have RNase H activity or it can not have RNase H activity (Column 8 lines 17-24). The instant specification does not provide support for the narrower limitation of only reverse transcriptase with RNase H activity.

These amendments to the claims, therefore, constitute new matter.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

9. Claims 112-120, 123-130, 143-145 are rejected under 35 U.S.C. 102(b) as being anticipated by Scheele (US Patent 5162209 November 10, 1992).

With regard to Claim 112, step a, Scheele teaches providing a first DNA strand (e.g. a DNA molecule of interest) (column 3 lines 25).

With regard to step b, Scheele teaches contacting the DNA with dNTPs (e.g. nucleic acid precursors) (Column 4 lines 20-22). Scheele teaches a primer comprising an RNA segment (Column 3 lines 33-40). Scheele teaches a method of adding E. coli DNA polymerase I (e.g. effective amount of nucleic acid producing catalyst) (column 4 lines 14-15). Scheele teaches a method of adding RNase H (Column 4 lines 25).

With regard to step c, Scheele teaches a method of carrying out synthesis in the presence of the RNA primer to generate a polynucleotide comprising an RNA/DNA hybrid (Column 3 lines 30-40 and Figure 5).

With regard to step d, Scheele teaches a method of digesting the substrate with RNase H to remove the ribonucleic acid segment of the extended primer (Column 3 lines 30-40, column 4 lines 25-28, and Figure 5). Scheele teaches that the method can by adapted to permit amplification of the sample of dsDNA by PCR methodology

(column 8 lines 58-60). Scheele teaches that the reagents of the RNA primer, DNA target, dNTPs and Taq are placed into a PCR machine with the appropriate number of PCR temperature cycles (column 8 lines 65-69). Therefore in a PCR cycle the resultant dsDNA of step c would be denatured such that the strands of DNA produced which are identical to the DNA of interest can be used in the PCR cycle to produce more copies of the DNA of interest.

With regard to Claim 113, Scheele teaches that the primers comprise unmodified nucleotides because Scheele teaches the primers comprise nucleotides (Figure 5 step 3).

With regard to Claim 114, Scheele teaches that the primer includes a portion with that is complementary to an oligonucleotide tail added to the 3' end of the target DNA template (column 3 lines 25-35). Therefore the primers include a sequence which is complementary to the tail and therefore not complementary to the sequence of the DNA molecule of interest (e.g. the tail is added to the DNA target of interest but the tail is not considered the DNA which is of interest to be amplified) (Figure 5 and column 3 lines 25-40).

With regard to Claim 115, Scheele teaches that the primers comprise at least 5 nucleotides (column 3 lines 56-57).

With regard to Claim 116, Scheele teaches that the primer can include DNA and RNA because Scheele teaches that only some of the nucleotides of the primer are RNA (Column 3 lines 40-45).

With regard to Claim 117, Scheele teaches that the nucleic acid producing catalyst is a DNA polymerase (column 4 lines 14-15).

With regard to Claim 118, Scheele teaches that the DNA polymerase is E. coli DNA polymerase I (Column 4 lines 14-15).

With regard to Claim 119, Scheele teaches that the polymerase can also include Taq polymerase (Column 8 lines 66).

With regard to Claim 120, Scheele teaches that the nucleic acid precursors can be labeled (column 8 lines 37-38).

With regard to Claim 123, step a, Scheele teaches providing a first DNA strand (e.g. a DNA molecule of interest) (column 3 lines 25).

With regard to step b, Scheele teaches contacting the DNA with dNTPs (e.g. nucleic acid precursors) (Column 4 lines 20-22). Scheele teaches a primer comprising an RNA segment and a DNA segment by teaching that some of the nucleotide sequence of the primer is an RNA sequence and therefore the rest of the nucleotides would be DNA (e.g. a copolymer primer) (Column 3 lines 33-40). Scheele teaches a method of adding E. coli DNA polymerase I (e.g. effective amount of nucleic acid producing catalyst) (column 4 lines 14-15). Scheele teaches a method of adding RNase H (Column 4 lines 25).

With regard to step c, Scheele teaches a method of carrying out synthesis in the presence of the RNA primer to generate a polynucleotide comprising an RNA/DNA hybrid (Column 3 lines 30-40 and Figure 5).

With regard to step d, Scheele teaches a method of digesting the substrate with RNase H to remove the ribonucleic acid segment of the extended primer (Column 3 lines 30-40, column 4 lines 25-28, and Figure 5). Scheele teaches that the method can by adapted to permit amplification of the sample of dsDNA by PCR methodology (column 8 lines 58-60). Scheele teaches that the reagents of the RNA primer, DNA target, dNTPs and Taq are placed into a PCR machine with the appropriate number of PCR temperature cycles (column 8 lines 65-69). Therefore in a PCR cycle the resultant dsDNA of step c would be denatured such that the strands of DNA produced which are identical to the DNA of interest can be used in the PCR cycle to produce more copies of the DNA of interest.

Scheele teaches a method of adding excess primer (e.g. multiple copies of the copolymer primer) (Column 8 lines 58-60). Scheele et al. teaches that once the dsDNA is generated RNase H is used to remove the RNA primer (column 9 lines 1-5). Therefore once the RNA segment from the primer is removed the template is used to amplify another target strand by using another copolymer primer.

With regard to Claim 124, Scheele teaches that the primers comprise unmodified nucleotides because Scheele teaches the primers comprise nucleotides (Figure 5 step 3).

With regard to Claim 125, Scheele teaches that the primer includes a portion that is complementary to an oligonucleotide tail added to the 3' end of the target DNA template (column 3 lines 25-35). Therefore the primers include a sequence which is

complementary to the tail and therefore not complementary to the sequence of the DNA molecule of interest (Figure 5 and column 3 lines 25-40).

With regard to Claim 126, Scheele teaches that the primers comprise at least 5 nucleotides (column 3 lines 56-57).

With regard to Claim 127, Scheele teaches that the nucleic acid producing catalyst is a DNA polymerase (column 4 lines 14-15).

With regard to Claim 128, Scheele teaches that the DNA polymerase is E. coli DNA polymerase I (Column 4 lines 14-15).

With regard to Claim 129, Scheele teaches that the polymerase can also include Taq polymerase (Column 8 lines 66).

With regard to Claim 130, Scheele teaches that the nucleic acid precursors can be labeled (column 8 lines 37-38).

With regard to Claim 143, step a, Scheele teaches providing a first DNA strand (e.g. a DNA molecule of interest) (column 3 lines 25).

With regard to step b, Scheele teaches contacting the DNA with dNTPs (e.g. nucleic acid precursors) (Column 4 lines 20-22). Scheele. teaches a primer comprising an RNA segment and a DNA segment by teaching that some of the nucleotide sequence of the primer is an RNA sequence therefore the primer sequence would include DNA (e.g. a copolymer primer) (Column 3 lines 33-40). Scheele teaches a method of adding E. coli DNA polymerase I (e.g. effective amount of nucleic acid producing catalyst) (column 4 lines 14-15). Scheele teaches a method of adding RNase H (Column 4 lines 25).

With regard to step c, Scheele teaches a method of carrying out synthesis in the presence of the RNA primer to generate a polynucleotide comprising an RNA/DNA hybrid (Column 3 lines 30-40 and Figure 5). The instant specification does not define isostatic conditions of temperature, buffer and ionic strength. Scheele teaches combining the primer and the DNA molecule in a reagent solution at a particular heat with buffers that have a particular ionic strength to produce at least one copy of the DNA molecule by extension of the primer (Column 8 lines 1-15). Therefore Scheele teaches a method of allowing the mixture to react under isostatic condition of temperature, buffer, and ionic strength.

With regard to step d, Scheele teaches a method of digesting the substrate with RNase H to remove the ribonucleic acid segment of the extended primer (Column 3 lines 30-40, column 4 lines 25-28, and Figure 5). Scheele teaches that the method can by adapted to permit amplification of the sample of dsDNA by PCR methodology (column 8 lines 58-60). Scheele teaches that the reagents of the RNA primer, DNA target, dNTPs and Taq are placed into a PCR machine with the appropriate number of PCR temperature cycles (column 8 lines 65-69). Therefore in a PCR cycle the resultant dsDNA of step c would be denatured such that multiple copies of the DNA could be copied from the DNA of interest.

With regard to Claim 144, Scheele teaches that the primer can include DNA and RNA (Column 3 lines 40-45).

With regard to Claim 145, Scheele teaches that the primer includes a portion with is complementary to an oligonucleotide tail added to the 3' end of the target DNA

template (column 3 lines 25-35). Therefore the primers include a sequence which is complementary to the tail and therefore not complementary to the sequence of the DNA molecule of interest (e.g. the tail is added to the DNA target of interest) (Figure 5 and column 3 lines 25-40).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

10. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

11. Claims 146-148 are rejected under 35 U.S.C. 103(a) as being unpatentable over Scheele (US Patent 5162209 November 10, 1992) in view of Schuster et al. (US Patent 5169766 December 8, 1992).

With regard to Claim 146, step a, Scheele teaches providing a first DNA strand (e.g. a DNA molecule of interest) (column 3 lines 25).

With regard to step b, Scheele teaches contacting the DNA with dNTPs (e.g. nucleic acid precursors) (Column 4 lines 20-22). Scheele. teaches a primer comprising an RNA segment and a DNA segment by teaching that some of the nucleotide sequence of the primer is an RNA sequence such that the rest of the sequence would be DNA (e.g. a copolymer primer) (Column 3 lines 33-40). Scheele teaches a method of adding E. coli DNA polymerase I (e.g. effective amount of nucleic acid producing catalyst) (column 4 lines 14-15). Scheele teaches a method of adding RNase H (Column 4 lines 25). Therefore Scheele teaches a method of adding a polymerase and RNase H to the sample and does not teach adding a reverse transcriptase having RNase H activity.

With regard to step c, Scheele teaches a method of carrying out synthesis in the presence of the RNA primer to generate a polynucleotide comprising an RNA/DNA hybrid (Column 3 lines 30-40 and Figure 5). The instant specification does not define isostatic conditions of temperature, buffer and ionic strength. Scheele teaches combining the primer and the DNA molecule in a reagent solution at a particular heat with buffers which would have particular ionic strength to produce at least one copy of the DNA molecule by extension of the primer (Column 8 lines 1-15).

With regard to step d, Scheele teaches a method of digesting the substrate with RNase H to remove the ribonucleic acid segment of the extended primer (Column 3 lines 30-40, column 4 lines 25-28, and Figure 5). Scheele teaches that the method can by adapted to permit amplification of the sample of dsDNA by PCR methodology (column 8 lines 58-60). Scheele teaches that the reagents of the RNA primer, DNA target, dNTPs and Taq are placed into a PCR machine with the appropriate number of PCR temperature cycles (column 8 lines 65-69). Therefore in a PCR cycle the resultant dsDNA of step c would be denatured such that multiple copies of the DNA could be copied from the DNA of interest.

With regard to Claim 147, Scheele teaches that the primer can include DNA and RNA (Column 3 lines 40-45).

With regard to Claim 148, Scheele teaches that the primer includes a portion with is complementary to a portion of the oligonucleotide tail added to the 3' end of the target DNA template (column 3 lines 25-35). Therefore the primers include a sequence which is complementary to the tail and therefore noncomplementary to the sequence of the DNA molecule of interest (e.g. the tail is added to the DNA target of interest) (Figure 5 and column 3 lines 25-40).

Scheele et al. teaches a method of producing copies of a DNA molecule using polymerase and RNase H, however, does not teach method steps of reverse transcriptase having Rnase H activity.

Schuster et al. teaches a method of amplification of nucleic acid molecules (abstract). With regard to Claim 146, Schuster et al. teaches that transcription can be done with a reverse transcriptase that has RNase H activity (column 8 lines 17-24).

Therefore it would be prima facie obvious to one of ordinary skill in the art to modify the method of Scheele et al. to replace the step of adding a polymerase and RNase H to the nucleic acid sample for a step of adding reverse transcriptase with RNase H activity as taught by Schuster et al. with a reasonable expectation of success. The ordinary artisan would be motivated to replace the step of adding a polymerase and RNase H to the nucleic acid sample for a step of adding reverse transcriptase with RNase H activity as taught by Schuster et al. because Schuster et al. teaches that if an enzyme with RNase H activity is used it is possible to omit a separate RNase H digestion step (Column 8 lines 17-24). Therefore the use of reverse transcriptase with RNase H activity would allow the ordinary artisan to perform the method of Scheele et al. with a reduced number of method steps because only reverse transcriptase with RNAse activity must be added to the target to initiate transcription rather than a polymerase and RNase H and thereby allow for a quicker production of DNA molecules.

12. Claims 133-140 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schuster et al. (US Patent 5169766 December 8, 1992) in view of Vary et al. (US Patent 4851331).

With regard to Claim 133, Schuster et al. teaches amplification of RNA (abstract). With regard to step a, Schuster et al. teaches a nucleic acid sample containing a RNA molecule of interest (Figure 2 1st step).

With regard to step b, Schuster et al. teaches contacting the RNA molecule with nucleic acid precursors (Column 7 lines 60-65). Schuster et al. teaches annealing primers which are complementary to the RNA molecule of interest (Figure 2), however, does not teach that these primers have an at least one ribonucleic acid segment. Schuster et al. teaches addition of a nucleic acid producing catalyst (e.g. DNA polymerase) (Figure 2). Schuster et al. teaches the addition of RNase H (Figure 2).

With regard to step c, Schuster et al. teaches a DNA copy form the RNA molecule of interest by binding of the primer (Figure 2 step 3).

With regard to step d, Schuster et al. teaches that the first DNA copy (e.g. the cDNA) is used a template to produce a double stranded nucleic acid (e.g. double stranded DNA).

With regard to step e, Schuster et al teaches destroying RNA with RNase H to produce the first DNA double strand copy. Schuster et al. teaches that RNA is transcribed and that the process can be continued to amplify multiple copies of the RNA molecule of interest (Figure 2).

With regard to Claim 134, Schuster et al. teaches a method wherein the primers comprise nucleotides (e.g. unmodified) (column 5 lines 55-60).

With regard to Claims 135-136, Schuster et al. teaches that the primers can comprise regions which can be used as a template for T7 RNA polymerase (column 8

lines 52-53); therefore these regions would encompass at least 1 noncomplementary nucleotides to the target.

With regard to Claims 138-139, Schuster et al. teaches the use of E. coli DNA polymerase I and Klenow polymerase (column 7 lines 15-20).

With regard to Claim 140, Schuster et al. teaches the use of Taq polymerase (column 7 lines 15).

However, Schuster et al. does not teach that the primer is comprised of RNA segments.

With regard to Claims 133 and 137, Vary et al. teaches that when using a primer-dependent DNA polymerase of eukaryotic origin primers having a 3' terminal ribonucleotide rather having a 3' terminal deoxynucleotide are more active (Column 9 lines 65-69 and column 10 lines 1-10). Vary et al. teaches that oligonucleotides can be comprised of both RNA and DNA (column 10 lines 5-10). The polymerase of Schuster et al. is E. coli DNA polymerase I which is a polymerase of eukaryotic origin.

It would have been prima facie obvious to one of ordinary skill in the art at the time of filing to modify the method of Schuster et al. to use a RNA/DNA primer as taught by Vary et al. in place of the DNA primer used to transcribe the RNA to cDNA. The ordinary artisan would be motivated to use a DNA primer with an end of ribonucleotide in order to have a more active elongation of the template region using E. coli DNA polymerase I. Vary et al. teaches that when using a primer-dependent DNA polymerase of eukaryotic origin primers having a 3' terminal ribonucleotide rather having a 3'

terminal deoxynucleotide are more active (Column 9 lines 65-69 and column 10 lines 1-10).

Conclusion

13. No claims are allowable over the cited prior art.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Katherine Salmon whose telephone number is (571) 272-3316. The examiner can normally be reached on Monday-Friday 8AM-430PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached on (571) 272-0735. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Katherine Salmon/
Examiner, Art Unit 1634

/Juliet C Switzer/

Primary Examiner, Art Unit 1634